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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,483	DAX ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,8,9,12 and 17-19* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 17-19* is/are rejected.

7)☒ Claim(s) *3-5,8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/17/03*. (p. 2)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' election of Group I subject matter with traverse is acknowledged but is not persuasive. Having a common class among some of the groups is not enough to preclude a restriction requirement since a search is determined by class and subclass for which there are many subclasses as indicated in the previous action. Additionally, there are many differing classes and subclasses especially for Group IV. Having an amide or amine group always present in the compounds is not enough structural similarity to place all of the compounds into 1 group, especially in view of the many differing issues of patentability that exist. See for example US'347 which is pertinent to group III in part when R3 is heterocycloalkyl and B1/B2 form an indane ring . Also see US'643 pertinent in a small part to Group IV when L=alkenylene and Z is phenyl.

For the above reasons the restriction is believed proper and is therefore made FINAL. To advance the prosecution applicants are requested to present claims directed to elected subject matter.

Claims 2,17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.In main claim 2 it should be made clear that the last "Z" choice only applies to last choice in"L" consistent with the specification and resulting spiro fusion intended.

2.In the definition of B1/B2 forming a 5 or 6-membered carbocyclic ring, it should be made clear that B1 **and/or** B2 are methylene. As recited only a 6-membered ring results.

3. Claims 18 and 19 are substantial duplicates of each other notwithstanding applicants' traverse to this rejection made in an earlier action by the previous examiner. ~~not materially change the scope~~. While applicant can present claims of varying degrees of protection one must comply with 35 USC 112. See MPEP 2111.02 which stresses that merely reciting an intended use for a structure is not accorded any weight where its exclusion from a claim would not destroy the completeness of the claim. Also note In re Tuominen 213 USPQ 89.

4. Claim 17 is of indeterminate scope for the following reasons. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to such a mode of action involves much experimentation since a negative response from one patient does

not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating obesity, does not reasonably provide enablement for remaining uses covered by claim 17. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. From a reading of the specification many diseases are embraced by this scope including all eating disorders, sleep disorders, memory loss, diabetes, etc. The notion that NPY5 antagonists are known for such a range of uses is not substantiated by the current state of the art such as Kehne, provided with this action. See especially Table 1 therein. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of in vivo efficacy by those skilled in the art. See for example, In re Ruskin 148 USPQ 221; Ex parte Jovanovics 211 USPQ 907. Any

evidence relied on by applicants must clearly show a reasonable expectation of in vivo success for any additional diseases that may still be embraced in response to this action. See MPEP. 2164.05(a).

Note also the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a),August 2000 edition which considers factors such as:

1) Breadth of the claims- The claims cover (but are not limited to) to a variety of unrelated uses including whole classes of disorders as discussed above;

2) Level of skill in this art- the examiner has pointed out above that drugs having the activity relied on herein are not known to have such a spectrum of clinical applications and thus the level of skill is low ;

3) State of the prior art- compounds similar/identical in structure (note Youngman applied below) has not demonstrated such a range of uses;

4) Working examples- There are no test(s) directed to the many uses pointed out above which are art-recognized for predicting ***in vivo*** efficacy .

Thus in view of the above the rejection is being applied.

Claims 2 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. The following reason applies:

1). The 3rd proviso excludes **less** that what was originally excluded. Note that the present proviso permits other "Z" choices for the elected piperidino "L" link which was excluded in the disclosure as originally filed. See specification on p.12 top paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Youngman (of record). The commonly assigned article describes a compound within the elected scope for uses based on NPY 5 antagonistic activity. See entry 7k in Table 1. Youngman is a competent reference since applicants are only accorded the instant filing date in view of the lack of compliance with 35 USC 112, par.one for the reasons set forth above in the 112 rejections.

Claims 3-5,8 and 9 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

EP'555 is cited in view of its similarity to instant compounds but note the "A" moiety is a phenyl or naphthyl group .

It is noted 2nd page of IDS filed 12/17/03 was not initialed by previous examiner. A signed copy is being provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

E Bernhardt

Emily Bernhardt
Primary Examiner
Art Unit 1624